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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,801

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,801	Applicant(s) MORINAGA ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments and arguments filed Jun. 26, 2009 are acknowledged and have been fully considered. Claims 1-7, 11-14, and 16-21 are now pending. Claims 8-10 and 15 are cancelled; claims 11 and 12 are amended; claims 1-7 are withdrawn. Claims 11-14 and 16-21 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The previous rejection of claims 11-14 and 16-21 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 11-14 and 16-21 under 35 U.S.C. 103(a) is maintained as discussed below.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-14 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MATSUDA (U.S. 2003/0114061; Filed Dec. 12, 2002; Reference #1 under U.S. Patent Application Publications on IDS dated Feb. 25, 2008) in view of CALHOUN (U.S. 2004/0115241; Filed Sep. 9, 2002).

1. Matsuda discloses adhesion preventative membranes (abstract) comprised of a first membrane made of a collagen nonwoven fabric layer that provides membrane strength (corresponding to the instantly claimed biodegradable base layer). This biodegradable base layer may be laminated with a coating layer, containing a mixture of

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collagen and hyaluronic acid that prevents adhesion. Thus, the first membrane is at least two layers and has a biodegradable base layer and an adhesion preventative layer (paragraphs [0091], [0092] and [0163]; Examples 1 and 3; claims 1 and 2).

2. Matsuda teaches that the adhesion preventative membranes of the invention can be used for prosthesis and as a prosthetic membrane for deficient parts or cut surfaces of membranous tissues in the living body, such as pericardium (paragraphs [0001], [0192], and [0198]). Matsuda teaches that the materials are suitable for various kinds of prosthetic materials that can be used in known manners (paragraphs [0003], [0192], [0196], and [0197]). Matsuda does not explicitly teach sandwiching an injured tissue by two membranes or by a tissue-sandwiching part of one membrane.

3. However, one of ordinary skill in the art would know to apply the adhesion preventative membranes in this way. The skilled artisan would readily appreciate that it is important to prevent adhesion to all of the surrounding tissues adjacent to a damaged membrane (i.e. on both sides) as taught by Matsuda (paragraphs [0092], [0094], and [0095]). Furthermore, methods using adhesion preventative membranes to sandwich a particular site were well-known at the time of the invention.

4. For example, Calhoun discloses anti-adhesion membranes for use with implants to prevent post-surgical adhesions between the implant and the surrounding tissue. Calhoun teaches a method of reducing adhesions resulting from a surgical implant comprising covering all the surfaces of the implant with a bioresorbable anti-adhesion membrane by sandwiching the implant within the membrane (paragraphs [0023] and [0028]; claims 1 and 5). Since the implant taught by Calhoun is the potential cause of

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the adhesions to be prevented, one of ordinary skill in the art would readily envisage sandwiching an injured or deficient tissue (which is also the cause of the adhesions to be prevented) by the similar adhesion preventing membranes of Matsuda.

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to sandwich an injured or deficient tissue between two membranes taught by Matsuda. One would have been motivated to do so since Matsuda does not disclose specific methods for the use of the disclosed membranes, but rather teaches that the inventive membranes can be used in known manners and in accordance with known methods (paragraphs [0192], [0196], and [0197]). While it is well within the skill of the ordinary artisan to determine the optimal placement of adhesion preventing membranes at the sites at which adhesion prevention is desired, the artisan would be motivated to look to the literature for guidance in the absence of specific teachings by Matsuda. Calhoun teaches a method of preventing adhesions using bioresorbable membranes to sandwich the cause of the adhesions. Therefore, an ordinary artisan would have had a high expectation of success by using the membranes of Matsuda to sandwich a damaged or deficient membrane (i.e. the cause of adhesions) as taught by Calhoun, to provide a suitable prosthetic membrane structure for healing of the damaged or deficient membrane. Claims 11-14 are obvious over Matsuda and Calhoun.

6. As stated above, Matsuda teaches adhesion preventive membranes having a base layer of collagen nonwoven fabric and having a coating layer (i.e. an adhesion preventive layer) containing a mixture of collagen and hyaluronic acid (paragraphs

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[0091], [0092] and [0163]; Examples 1 and 3; claims 1 and 2). Furthermore, Matsuda teaches that the coating layer containing the mixture of collagen and hyaluronic acid is sponge-like or film-like (i.e. a sheet) (paragraphs [0021], [0027], [0037], [0038], [0088]; Examples 1 and 3). Thus, the combination of Matsuda and Calhoun renders claims 16-21 obvious as well.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Matsuda does not disclose applying two membranes to opposing sides of a tissue. Applicants' arguments imply that a second membrane is required by the instant claims. Applicants argue that there is no motivation to apply a second membrane in the cited references (response, p. 6-7).

It was acknowledged in the prior Office Action that, "Matsuda does not explicitly

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teach sandwiching an injured tissue by two membranes or by a tissue-sandwiching part of one membrane" (see paragraph 2 of p. 5 of the prior Office Action). In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Calhoun was cited for the teaching of the technique of sandwiching an adhesion prone area for the purpose of preventing said adhesions, which cures the deficiency in Matsuda.

It is noted that applicants' claims do not require a second membrane as incorrectly asserted by applicants. Applicants are reminded of the breadth of their claims, for example, option (B) which is recited in the alternative to option (A). Option (B) does not require two membranes. Rather, sandwiching an injured tissue with a single adhesion preventive membrane (i.e. a tissue sandwiching part) meets the claim language.

Applicants broadly assert that the teachings of both Matsuda and Calhoun represent the conventional methodology shown in Fig. 5 of the instant application (response, p. 7).

Applicants provide no evidence to support this assertion. Rather than being limited to the embodiment of instant Fig. 5, as asserted by applicants, Calhoun's cited teachings state:

"The membrane may be formed or applied on or over the implant or device using any of a number of techniques including, but not limited to, wrapping, interweaving, blanketing, draping, taping, adjacent placement, juxtaposed positioning, and sandwiching." (emphasis added; see paragraph [0023])

Thus, Calhoun teaches arranging the membranes in precisely the same way as claimed by applicants.

Applicants argue that there is no reason to combine the two references (response, p. 7-8).

The examiner provided explicit motivation for why one would combine the two references, which motivation has been ignored by applicants. In the prior Office Action it was stated, "One would have been motivated to do so since Matsuda does not disclose specific methods for the use of the disclosed membranes, but rather teaches that the inventive membranes can be used in known manners and in accordance with known methods (paragraphs [0192], [0196], and [0197])." (see paragraph 5 of the prior Office Action). Because Matsuda does not explicitly discuss the "known manners and methods", one would be motivated to look to the literature for further guidance. In addition to this previously presented reasoning, both Matsuda and Calhoun are directed to highly similar problems in the art, namely preventing adhesions using adhesion preventative membrane materials. One of skill in the art would clearly have had reason to look to, and combine, these teachings.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 112 (2nd Paragraph)

Claims 11-14 and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 and 16-21 are indefinite in the recitation, "...wherein the first membrane has a biodegradable base layer and an adhesion preventive layer, the biodegradable base layer and the adhesion preventive layer being provided respectively at outermost surfaces thereof of the first membrane" in claim 11. It is noted that the claim requires sandwiching an injured tissue with the membrane. In such a configuration, the artisan would understand the membrane to have only one outermost surface (i.e. that facing away from the injured tissue). Thus, it is unclear how both the biodegradable base layer and the adhesion preventative layer can both be present at the same (outermost) surface. The metes and bounds of the claims are unclear.

Summary/Conclusion

Claims 11-14 and 16-21 are rejected; claims 8-10 and 15 are cancelled.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643